

K050239



MAP 16 4/3

**510(k) Summary**  
**EM Diagnostics, Inc.,**  
**EMD Thermography System, Model RTM-02-RES**

**Date Prepared: 20 February 2006**

<b>Sponsor</b>	<b>Consultant</b>	
Mr. Orest Lozynsky EM Diagnostics, Inc. 111 Center St., Suite 1200 Little Rock, AR 72201 501-907-7744 F 907 7745 orest@emdlr.com	Mr. Richard Keen Compliance Consultants 1151 Hope Street Stamford, CT 06907-1659 203 329 2700 F 203 329 2345 rkeen@fda-complianceconsultants.com	
<b>Device Name</b>	<b>Predicate Devices</b>	
Proprietary Name: EMD thermography system, Model RTM-01-RES	KO03130 Regutherrn 952	
Common Name Thermography System	K971956, CRT 2000 Thermographic System	
	Werner Eidam. Medizin-Technologie GmbH	
<b>Class I device</b>	<b>Regulation Number</b>	<b>Product Code</b>
Telethermographic systems	21 CFR 884.2980	LHQ
liquid crystal thermographic systems	21 CFR 884.2982	IYM

**Obstetrical and Gynecological Device Panel**

**Device Description**

The EMD Thermography System is an infrared frequency thermography system, designed to provide non-invasive temperature measurements of sites on the human body. The device includes an infrared sensor for measuring temperatures at specific areas on the skin surface. This sensor are placed in contact with the skin to perform measurements. A personal computer and software is for analysis of the temperature measurements and display of the temperature distributions.

**Intended Use**

The EMD Thermography System is an infrared spectrum thermography system used to measure, record and view thermal patterns generated by the human body. It is intended for use as an adjunct to other clinical diagnostic procedures in the screening and diagnosis of abnormalities where a physician chooses to use thermography.

EM Diagnostics, Inc.  
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Tel: 501.907.7744  
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### **Technological Characteristics And Substantial Equivalence**

The EMD Thermography System is substantially equivalent to predicate direct contact thermography systems. The EMD Thermography System and the predicate devices have fundamentally the same indications for use. All of these devices are designed to be used to measure temperature.

### **Performance Testing**

Information submitted in this premarket notification for the EMD Thermography System includes results of testing for electrical safety, EMI/EMC, temperature measurement accuracy and results of clinical testing.

20 February 2006

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Mr. Orest Lozynsky

Date

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Little Rock, AR 72201  
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 9 - 2006

EM Diagnostics, Inc.  
% Mr. James R. Veal  
Vice President, Strategic and Technical Assistance  
Medical Device Consultant  
49 Plain Street  
NORTH ATTLEBORO MA 02760

Re: K050239

Trade/Device Name: EMD Thermography System, Model RTM-02-RES  
Regulation Number: 21 CFR 884.2980  
Regulation Name: Telethermographic system  
Regulatory Class: I  
Product Code: LHQ  
Dated: February 20, 2006  
Received: February 22, 2006

Dear Mr. Veal:

This letter corrects our substantially equivalent letter of March 16, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Joyce M. Whang, Ph.D.  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

## Indications for Use

510(k) Number (if known): K050239

Device Name: EMD-Thermography System, Model RTM-02-RES

### Indications for Use:

The EMD Thermography System, Model RTM-02-RES is an infrared spectrum thermography system used to measure, record and view thermal patterns generated by the human body. It is intended for use as an adjunct to other clinical diagnostic procedures in the screening and diagnosis of abnormalities where a physician chooses to use thermography.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

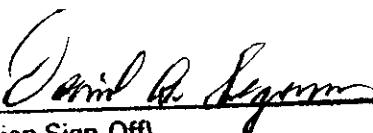
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K050239